IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

EXELIXIS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 19-2017 (RGA) (SRF)
	)	**CONSOLIDATED**
MSN LABORATORIES PRIVATE LIMITED and MSN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

PLAINTIFF'S REPLY POST-TRIAL BRIEF ON MSN LABORATORIES PRIVATE LIMITED AND MSN PHARMACEUTICALS, INC'S INFRINGEMENT OF U.S. PATENT NO. 8,877,776

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I. INTRODUCTION

The evidence presented at trial established four critical and unrefuted facts that prove MSN's Tablets contain Form N-2.

- ***First,*** ^{13}C-SSNMR testing demonstrated Form N-2 in MSN's API after four weeks and eight weeks of exposure to accelerated conditions. MSN does not dispute this.
- ***Second,*** more sensitive ^{19}F-SSNMR testing (testing specifically described in the specification) (*see, e.g.,* JTX-001 FIG 14, col. 11, ll. 17-18) demonstrated Form N-2 in MSN's API after only one week of exposure to accelerated conditions. MSN does not dispute this.
- ***Third,*** variable rates of conversion from Form S to Form N-2 among the three lots tested using ^{19}F-SSNMR demonstrated that Form N-2 was present in MSN's API at the outset (i.e., before accelerated conditions). Although MSN does not concede this point, it ignores the unrebutted evidence Dr. Munson provided on this issue.
- ***Fourth,*** if Form N-2 is present in MSN's API, then it is necessarily present in MSN's Tablets. It does not disappear. MSN does not and cannot dispute this logic, logic predicated upon basic scientific principles.

MSN's attempts to respond to Exelixis' infringement proof miss the mark. MSN makes much of the fact that there is no direct testing evidence showing the presence of Form N-2 in MSN's Tablets. But MSN concedes, as it must, that an infringement case may be established using circumstantial evidence and the case law consequently holds that testing of a final drug product is not required to prove infringement. MSN Rebuttal at 9; *see also Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1372-74 (Fed. Cir. 2009). Indeed, testing the API to determine

the polymorphic stability of the API in the tablets is consistent with the practices of both parties in this case.

MSN also attacks Dr. Munson's use of accelerated conditions, accusing him of artificially creating Form N-2 in the MSN API. MSN's criticism ignores the substantial evidence demonstrating that the accelerated conditions used by Dr. Munson (i) are standard in the industry, (ii) were used by both Exelixis and MSN for the same purpose (i.e., to assess the polymorphic stability of their respective cabozantinib products), and (iii) are consistent with the heat and humidity ranges to which MSN's API is actually exposed to in the real world. MSN cannot therefore shoehorn the facts of this case into those at issue in *Lundbeck*, where testing was not representative of conditions to which the API would be exposed and samples were mishandled. *H. Lundbeck A/S v. Lupin Ltd.,* C.A. No. 18-88-LPS, 2021 WL 4944963 (D. Del. Sept. 30, 2021), *appeal filed,* No. 22-1194 (Fed. Cir. Nov. 29, 2021) and *appeal filed,* No. 22-1208 (Fed. Cir. Dec. 1, 2021).

Similarly, MSN's suggestion that Exelixis' reliance on the "rate of conversion" is an unsupported "new[]" theory is simply wrong. MSN Rebuttal at 17-18. Dr. Munson testified unequivocally that the variable rates of conversion across three different lots of MSN API tested using ^{19}F SSNMR demonstrated that Form N-2 was present in those samples from the outset (i.e., before accelerated conditions). FOF ¶¶ 60-61. MSN simply chose not to respond with its own testing or even with rebuttal expert testimony. Dr. Munson's testimony on this issue was unrebutted.

Finally, MSN contends that its own XPRD testing shows "the lack of Form N-2 in MSN's Tablets." MSN Rebuttal at 9. But that is again simply incorrect because the XPRD testing on

which MSN seeks to rely (i) is not the only way to establish infringement of the asserted claim; and (ii) was not designed to either detect or rule out the presence of Form N-2.

In the end, MSN, as it admits, attempted to develop a generic version of Exelixis' lifesaving cabozantinib by designing around the asserted claim. It was unsuccessful; it could not both produce a generic version of that drug that would satisfy the FDA and provide the therapeutic benefits of that drug without producing a product containing Form N-2. To prove that MSN failed, required disciplined and detailed testing by Exelixis to demonstrate the presence of Form N-2 in the MSN API at the outset, and the increasing presence of Form N-2 in MSN's Tablets over time. That is precisely what the evidence demonstrates, and that proves infringement.

II. ARGUMENT

A. Testing of MSN's API to Prove Infringement Was Appropriate and Consistent With Standard Practice

MSN does not (and cannot) dispute that "Exelixis is free to try to prove up its case using circumstantial evidence." MSN Rebuttal at 9. Indeed, it is well-settled that direct testing of the finished product is not required, including in the case of claims directed to pharmaceutical compositions. *See, e.g., Martek Biosciences Corp.,* 579 F.3d at 1372-74; *see also Bristol-Myers Squibb Co. v. Aurobindo Pharma USA Inc.,* 477 F. Supp. 3d 306, 346-47 (D. Del. 2020) (finding infringement of pharmaceutical composition claim where there was no testing of the tablet), *aff'd sub nom. Bristol-Myers Squibb Co. v. Sigmapharm Lab'ys, LLC,* 858 F. App'x 359 (Fed. Cir. 2021). And, for good reason. Common sense dictates that when it is "***standard practice***" to identify presence of the claimed component ***prior to formulation***—identifying the infringing component in the finished product ***is not required***. *Novartis Pharms. Corp. v. Par Pharm., Inc.,* 48 F. Supp. 3d 733, 743-44 (D. Del. 2014) (testing identifying the claimed component prior to its inclusion in the formulated pharmaceutical composition was sufficient because there were

"practical difficulties" in testing the formulated pharmaceutical composition), *aff'd sub nom. Novartis Pharms. Corp. v. Watson Lab'ys, Inc.,* 611 F. App'x 988 (Fed Cir. 2015).

Accordingly, MSN's assertion that the lack of direct evidence of Form N-2 in the MSN Tablets "should nearly close the door on the infringement inquiry," (MSN Rebuttal at 8-9), is wrong as a matter of law and an invitation to legal error. The undisputed evidence at trial established that the standard practice for identifying crystalline content is to do so ***before*** the API is formulated into a tablet. Neither MSN nor Exelixis tested for the presence of Form N-2 after the API was formulated into a tablet. FOF ¶ 47. Rather, the ***only*** stage at which either company conducts testing on its API is before tablet formulation, *i.e.,* they test the API. FOF ¶ 47. This is due to the practical difficulties of testing for a crystalline form in a tablet after the API has been formulated with other ingredients. As Dr. Munson explained, more than 75% of MSN's Tablets consist of material that is not cabozantinib. FOF ¶ 64. And the remaining percentage of MSN's Tablets comprises at least three different crystalline forms of cabozantinib.[1] FOF ¶ 64. Signals from these other materials and multiple crystalline forms of cabozantinib in the MSN Tablets thus interfered with Dr. Munson's ability to clearly discern a signal for Form N-2. FOF ¶ 64. Under such circumstances, just as in *Novartis,* evidence showing Form N-2 in MSN's API is sufficient to establish infringement. *Novartis Pharms. Corp.,* 48 F. Supp. 3d at 743-44.

B. The Accelerated Conditions Used By Dr. Munson Were Appropriate

Having conceded that ^{13}C-SSNMR testing shows that Form N-2 is present in MSN's API after 4 and 8 weeks, MSN argues that the accelerated conditions used by Dr. Munson are not "representative" and created a "perfect storm" that caused N-2 to form. MSN Rebuttal at 19-21.

[1] Dr. Munson testified that his ability to detect Form N-2 was not only obscured by Form S, but by at least one *different form* of cabozantinib that is neither Form S nor Form N-2. FOF ¶ 51.

In fact, the evidence established that accelerated conditions are commonly used in the pharmaceutical industry for testing the stability of crystalline forms of API, including polymorphic stability. FOF ¶¶ 52-56.

First, MSN's suggestion that it was unnecessary for Dr. Munson to use accelerated conditions at all because the MSN API samples were already "aged," (MSN Rebuttal at 22-23), is incorrect. The API that Dr. Munson received from MSN had been sitting ***in a refrigerator*** for 36 months. However, as the MSN API does not have an expiry date,[2] the storage of MSN API samples for 36 months under refrigeration does not indicate that the API was "aged" or "expired". Furthermore, refrigerated storage does not represent the conditions and opportunities for conversion from formulation to manufacturing to consumption that MSN's API will experience in the real world. In fact, the evidence showed that, in the real world, the MSN API will be taken out of the refrigerator, be exposed to the environment multiple times during the process of manufacturing the API into a tablet, and the transportation of the API from India to the United States, where it will sit on a shelf for some period of time before being further transported and then dispensed to patients (who will also store it for some period of time). FOF ¶¶ 33-35. To understand how the MSN API will behave over time and under variable conditions as it is incorporated into the MSN Tablets and travels the stream of commerce, Dr. Munson used accelerated conditions consistent with typical industry practices, including by Exelixis and MSN. FOF ¶¶ 19-21, PTX-739 ("The purpose of stability testing is to provide evidence on how the quality of a drug substance or drug product varies with time . . ."); Tr. 59:14-60:12 (Shah) (describing submission of

[2] The proposed retest period is 30 months. FOF ¶ 34. This does not mean that MSN's API has a shelf life of 30 months; it simply means that MSN's API must be retested for stability at that time. *Id.* The accelerated conditions used by Dr. Munson are relevant for observing the behavior of the API over its entire shelf life, which may be significantly longer than its initial retest period, including when it is stored at temperatures significantly higher than a refrigerator.

accelerated stability testing data submission to the FDA); PTX-194 (describing MSN stability testing using 40°C/75% relative humidity (RH) for three months); Reply FOF ¶ 1 ("accelerated conditions are conditions that were going to be slightly higher humidity, slightly higher temperature, something that may be representative of potential storage conditions or also manufacturing conditions").

Second, MSN's assertion that accelerated conditions are not used to test for "polymorphic stability" (MSN Rebuttal at 19) is flatly contradicted by the record. The evidence at trial established that both Exelixis and MSN use accelerated conditions to test for ***polymorphic*** stability in the ordinary course. Indeed, in a document titled "Polymorphic Stress Study," MSN used higher heat and higher humidity than Dr. Munson did to test for the polymorphic stability of its cabozantinib API. FOF ¶ 44; *see also* PTX-180 at 2 ("Purpose: To have a report for the polymorphic stress study of Cabozantinib (S)-Malate Form -S"; "Scope: To know the polymorphic consistency under stress study of Cabozantinib (S)-Malate Form S"). Likewise, Exelixis tested its cabozantinib API under accelerated conditions similar to those used by Dr. Munson. FOF ¶¶ 54, 55. As Dr. Shah testified, such testing was "extremely important" to ensure that Form N-2 would be stable in a real-world setting. FOF ¶ 55. These studies by both MSN and Exelixis used accelerated conditions that were similar or identical to those used by Dr. Munson. They conclusively establish that Dr. Munson's accelerated conditions were reasonable and appropriate.[3]

Third, MSN ignores the real-world evidence in contending that the heat and humidity parameters used by Dr. Munson were not representative of conditions to which its API is exposed.

[3] For this reason, MSN's reliance on *Glaxo* is misplaced. Dr. Munson did not "adulterate[]" (MSN Rebuttal at 2, 5 and 19) MSN's API. He tested it to determine how it would behave in the real world over time—the same way that MSN and Exelixis each tested its own API during the development process.

MSN Rebuttal at 23-26. For example, contrary to MSN's assertion that its API never endures relative humidity above 45-55%, Dr. Munson testified that the MSN API is wet (i.e., exposed to 100% relative humidity) at least three times during MSN's tablet manufacturing process including: (i) during the wet granulation step; (ii) when the granules enter the drying stage; and (iii) at the coating step, when the API is exposed to a liquid (i.e., 100% relative humidity) substance. Reply FOF ¶ 3. MSN never presented any contrary evidence. Similarly, MSN's assertions regarding the temperature used in its tablet manufacturing ignores two key undisputed facts: (i) that MSN's ANDA manufacturing specifications plainly allow for temperatures as high as 40°C; and (ii) that the actual inlet temperature of the hot air that is applied to MSN's granulated API is 60°C.[4] FOF ¶¶ 38-41. Of course, those are higher temperatures than the 40°C used by Dr. Munson. Moreover, while MSN argues that Dr. Munson should have used different accelerated conditions (MSN Rebuttal at 29-31), it presented and cites no evidence whatsoever that using different conditions, such as 25°C/60% relative humidity (instead of 40°C/75% relative humidity) or sealed containers, would have made any difference. Indeed, as Dr. Shah testified, Exelixis tested its cabozantinib API under a variety of accelerated conditions, including at temperatures and relative humidity lower than and higher than used by Dr. Munson, in both sealed and unsealed containers—***and got the same result each time***. Reply FOF ¶ 3. MSN's suggestion that applying different accelerated conditions would have yielded different results is purely speculative.

Finally, MSN's contention that the accelerated conditions created a "perfect storm" that caused the formation of Form N-2 in MSN's API is based solely on Dr. Steed's conjecture and contradicted by the record. MSN Rebuttal at 19-21, 36. As explained in Section II.C., the evidence

[4] Based on this inlet temperature, Dr. Munson testified that the API could also experience temperatures at the drying bed up to 60°C during other portions of the manufacturing process. Reply FOF ¶ 4.

established that Form N-2 is present in MSN's API from the outset. The evidence also established myriad reasons why MSN's Form S is uncontrolled and unstable, and therefore readily converts to Form N-2: (i) Form S has a lower and broader melting range than Form N-2; (ii) Form S is hygroscopic, which Dr. Steed admits makes it more likely to convert to other forms; (iii) Form S has a lower initial transition temperature; and (iv) Form S is more soluble than Form N-2. FOF ¶¶ 36-37.[5]

This case is not analogous to *Lundbeck*, as MSN repeatedly suggests. MSN Rebuttal at 3, 16 (n.2), 17 (n.4), 21, 33-34. Neither *Lundbeck* nor any other case has ever held that accelerated conditions are *per se* improper or cannot be used to support an infringement opinion. Rather, under the very specific facts of *Lundbeck*, accelerated conditions of 40°C and 75% relative humidity were criticized because they were higher than what the ANDA product was exposed to during the manufacturing processes. *Lundbeck*, 2021 WL 4944963 at *97 (noting that the ANDA product was exposed to "not more than 25°C and not more than 45% relative humidity"). That simply is not the case here. Furthermore, the court in *Lundbeck* found that the plaintiffs had mishandled the Sigmapharm API samples prior to testing, (*Lundbeck*, 2021 WL 4944963, at *98-99) whereas MSN raised no similar concerns regarding Dr. Munson's sample handling (FOF ¶48).

C. ^{19}F-SSNMR Testing Established That Form N-2 Is Present in MSN API at the Outset

MSN takes issue with Dr. Munson's opinion that N-2 is present in MSN's API at the outset, claiming that his "rate of conversion" theory is new and unsupported. MSN Rebuttal at 17-18.

[5] Dr. Steed failed to provide any basis for or explanation of his speculative one sentence of testimony that there are stabilizing excipients in the formulated API that would prevent conversion to Form N-2. MSN Rebuttal at 20.

MSN's criticisms are meritless. Exelixis provided expert testimony and documentary evidence on this issue, which MSN and its expert failed to rebut.

Dr. Munson compared ^{19}F-SSNMR data from three lots of MSN API. FOF ¶ 60. In doing so, he observed that the rate of conversion to Form N-2 was different for each lot.[6] FOF ¶ 60. Based on that observation, Dr. Munson concluded that Form N-2 must be present in the MSN API at the outset, as only that could explain the different rates in the formation of N-2 over time. FOF ¶¶ 62-63. The relevant ^{19}F SSNMR spectra, which MSN criticizes Dr. Munson for not addressing (MSN Rebuttal at 17), were admitted as exhibits with his direct testimony and can be found at PTX-829 and PTX-785B. Dr. Munson clearly explained his analysis of the spectra to the court:

> [W]e looked at Lot 7, we looked at Lot 8, and we looked at Lot 9. They all had different rates of conversion which tells me that there are different amounts of the Form N-2 that was present initially in those three different lots. And, in fact, Lot 9 converted about half the rate of Lot 7 did. ***And that's a good indication of the fact that you've got different rates of conversion indicating different levels of the Form N-2 initially present***.

Trial Tr. 67:8:23 (emphasis added); *see also* Trial Tr. 158:11-15 ("Q: If there were no N-2 present in the samples at the beginning, would you see different rates of conversion in these slides? A. No. In fact, the rate of conversions would be the same."); PTX-829 and PTX-785B. That does not render—as MSN suggests—this evidence conclusory or speculative. Dr. Munson presented a concrete opinion supported by SSNMR spectra and testimony explaining the basis for his opinion. MSN failed to rebut this opinion with any contrary evidence or testimony from its own expert, Dr. Steed. That leaves Dr. Munson's opinion unrebutted.

D. MSN's XRPD Testing Does Not Undermine Exelixis' Proof of Infringement

[6] MSN criticizes Dr. Munson for not quantifying the amount of N-2 present in each of the three MSN lots. MSN Rebuttal at 18. Absolute quantification of N-2 was not necessary for Dr. Munson to observe the *rate of conversion* of MSN API to Form N-2. FOF ¶ 60.

MSN's expert admitted that MSN's XRPD testing "was not designed to rebut" Dr. Munson's SSNMR testing. FOF ¶ 67. Ignoring that concession from its expert, MSN now tries to recast its XRPD testing as "direct evidence … proving the lack of Form N-2." MSN Rebuttal at 9. That is incorrect and contradicted by the record.

First, claim 1 of the '776 patent provides alternative ways of establishing the presence of Form N-2. Either XRPD testing or ^{13}C-SSNMR testing is sufficient to prove infringement. FOF ¶ 24. MSN cannot avoid the plain language of the claim. An XRPD test result that does not detect Form N-2 is merely an alternative test; it does not undermine or contradict ^{13}C SSNMR test results establishing its presence.

Second, it is evident on the face of the XRPD test results on which MSN seeks to rely that they were not designed to (nor can they) rule out the presence of Form N-2. As an initial matter, the graphics in MSN's brief compare XRPD testing of MSN's Tablets and API with XRPD tests of pure Form N-2 (MSN Rebuttal at 7, 10).[7] That comparison does not demonstrate that MSN's XRPD testing was sufficiently sensitive to determine whether any amount of Form N-2 is present in the MSN Tablets, which is all the asserted claim requires. FOF ¶ 24. Exelixis has never contended that MSN's ANDA product contains solely Form N-2 and no other crystalline forms, so it proves nothing to establish that MSN's Tablets and API are not the same as pure Form N-2.

Moreover, MSN never established that its XRPD testing would be sensitive enough to detect Form N-2 in MSN's Tablets. Indeed, the evidence was to the contrary. For example, while MSN touts XRPD as the "gold standard" (MSN Rebuttal at 4), both Dr. Munson and Dr. Steed

[7] MSN should be prohibited from presenting its analysis on page 7-8 of its Rebuttal Brief, because that analysis was not included in Dr. Steed's report, and when Dr. Steed was asked in his deposition whether he was going to provide an opinion based on the identified peaks for Form S from the MSN patent (DTX-495), he said he was not. Ex. 1, Steed Dep. Tr. at 397:18-398:8. This evidence was objected to at trial. Trial Tr. at 293:18-296:15.

agreed that there are circumstances where SSNMR is the preferred technique to identify a particular crystalline form—especially in situations, like here, where there are multiple forms in the sample. FOF ¶ 16. As Dr. Munson explained, SSNMR is more suitable than XRPD here because Form N-2 is initially present in smaller amounts in a sample containing a larger amount of Form S. Opening Br. at 21; FOF ¶¶ 16, 68.[8] Unlike XRPD, SSNMR is able to filter the signal from Form S, thereby enhancing the ability to detect Form N-2 when Form S is also present.

Additionally, as Dr. Munson explained, MSN's XRPD data was not "sufficiently sensitive," in part because it associated very broad peaks with MSN's Form S. FOF ¶ 68. The breadth of the Form S peaks in the MSN data—combined with the inability to filter out Form S using XRPD—does not allow one to conclude one way or another whether Form N-2 is present. FOF ¶ 68. In an effort to address the shortcomings of its XRPD evidence, MSN argues that peak overlap is not a "valid concern" with XRPD. MSN Rebuttal at 8. But this assertion relies upon a general statement by Dr. Steed regarding XRPD testing where some regions of the spectrum do not overlap. Tr. 285:18-286:9 (Steed). In making those statements, Dr. Steed did not address the specific XRPD testing at issue here, which features very broad peaks for Form S as discussed by Dr. Munson. *Id.* MSN thus failed to present any evidence that its XRPD testing would be capable of distinguishing between Form N-2 and Form S in a mixture. MSN's XRPD testing therefore does not rebut Dr. Munson's SSNMR testing or his opinion that the MSN API material is so highly unstable and uncontrolled that it contains ***multiple*** crystalline forms, including Form S, Form N-2, and yet another crystalline form that interferes with the ability to detect Form N-2.

[8] As explained above, infringement can be established based on the presence of ***any amount of Form N-2.*** MSN does not argue otherwise.

Contrary to MSN's assertion, this case is not analogous to *Astellas*. MSN Rebuttal at 11 (citing *Astellas US LLC v. Hospira*, C.A. No. 18-cv-1675, 2022 WL 1591277 (D. Del. May 19, 2022), *appeal filed,* No. 22-1878 (Fed. Cir. June 7, 2022)). In that case, both the DMF and ANDA release specifications required an XRPD analysis that (1) showed a pattern that conforms to the Form G reference pattern; and (2) showed that "no peaks are observed for other solid forms." *Astellas*, 2022 WL 1591277, at *28. Thus, the specification expressly excluded the crystalline form of the asserted claim in that case by stating that specific peaks associated with that form must not be present. *Id*. By contrast, MSN's specification in this case does no such thing; it does not require the absence of any XRPD peaks associated with Form N-2. Instead, all that it requires is the presence of four peaks associated with Form S.[9] FOF ¶ 47. Because Form S and Form N-2 can both be present in the same sample, and may actually overlap with one another, verifying the presence of peaks associated with Form S by XRPD alone does not and cannot rule out the presence of Form N-2.

E. MSN Will Induce Infringement of Claim 1 of the '776 Patent

MSN's only response to Exelixis' proof of indirect infringement is that (i) there is no direct infringement; and (ii) MSN had no knowledge of potentially infringing uses because its internal studies concluded that "Form S is stable under [all] stress study conditions." MSN Rebuttal at 34-35. For all the reasons set forth above and in Exelixis' opening brief, MSN has knowledge of and/or is willfully blind to the fact that there is direct infringement of claim 1 of the '776 patent because the MSN Tablets contain Form N-2. FOF ¶¶ 69-71. Accordingly, MSN will induce

[9] To the extent MSN attempts to rely on deposition testimony from Dr. Reddy to suggest that a pattern-to-pattern comparison is required (MSN Rebuttal at 11-12), that testimony cannot alter the plain language of the specification, which contains no such requirement. Moreover, when questioned in his deposition, Dr. Reddy testified that he did not "know exactly how they do the comparison." Tr. 254:4-6 (Reddy).

infringement of claim 1 of the '776 patent when it manufactures and supplies the MSN ANDA Products to Zydus for distribution in the United States.

III. CONCLUSION

For the reasons above, Plaintiff respectfully requests that the Court find that making, using, offering to sell, or selling in the United States, or importing into the United States MSN's Tablets will literally infringe the asserted claim of the '776 patent and, therefore, that the submission of MSN's ANDA infringes that claim under 35 U.S.C. § 271(e)(2)(A) and that upon FDA approval MSN will induce infringement of that claim under 35 U.S.C. § 271(b). Plaintiff further requests that the Court enter an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of MSN's ANDA shall be a date which is not earlier than the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled, and an order permanently enjoining MSN, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States MSN's Tablets until after the latest expiration date of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled.[10]

[10] Plaintiff's Complaint also seeks any appropriate relief under 35 U.S.C. § 285. *See* Compl., D.I. 1 in C.A. No. 19-cv-02017, Prayer for Relief at 9 (Oct. 29, 2019). No party has yet made a motion for fees, and, at this point, that issue is premature. Plaintiff may seek fees as permitted by the Federal Rules.

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August 5, 2022

CERTIFICATE OF SERVICE

I hereby certify that on August 5, 2022, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 5, 2022, upon the following in the manner indicated:

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